DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N–0589]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control Number 0910–0325)—Extension

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), (Public Law 103–396), amended the Federal Food, Drug, and Cosmetic Act to permit licensed veterinarians to prescribe extralabel use in animals of approved human and animal drugs. Regulations implementing provisions of AMDUCA are codified under part 530 (21 CFR part 530). A new provision under these regulations in § 530.22(b), permits FDA to establish a safe level for extralabel use in animals of an approved human or animal drug when the agency determines there is reasonable probability that this use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding a safe level is considered an unsafe use of a drug. In conjunction with the establishment of a safe level, the new provision permits FDA to request development of an acceptable residue detection method for an analysis of residues above any safe level established under part 530. The sponsor may be willing to provide the methodology in some cases, while in others, FDA, the sponsor and perhaps a third party, (e.g., a State agency or a professional association), may negotiate a cooperative arrangement to develop the methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug.

In the **Federal Register** of January 28, 2002 (67 FR 3903), the agency requested comments on the collection of information. In response, FDA received one comment. The comment asked whether the proposed collection of information was necessary for the proper performance of FDA functions including whether the information would have practical utility. As detailed,

FDA under this regulation is permitted to request development of an acceptable residue detection method for human or animal drugs used in an extralabel manner that could result in unsafe residues in edible products of the treated animal. If no acceptable analytical method is developed, FDA is permitted to prohibit extralabel use of the drug. Thus, this collection of information is necessary to permit licensed veterinarians to prescribe extralabel use of certain drugs.

The respondents may be sponsors of new animal drug(s), State or Federal Government, or individuals. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The Center for Veterinary Medicine (CVM) has not found circumstances to require the establishment of a safe level and subsequent development of

an analytical methodology. However, CVM believes there will be instances when an analytical methodology will be required.

Dated: 5-3-02

May 3, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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